as stent thrombosis. The Biolimus A9™ eluting stent platform (BES) releases biolimus from an abluminal biodegradable polymer, fully absorbed after 6-9 months. The LEADERS trial assessed the safety and efficacy of BES with an established stent platform releasing sirolimus from a durable polymer (SES) in a large scale, all-comers, non-inferiority trial. We report the 5 year follow-up and final report of the LEADERS study.
**Methods:** LEADERS is a multi-center, randomized, assessor-blind, non-inferiority trial performed at 10 European sites in an all-comers, "real world" patient population. A total of 1,707 patients were enrolled and randomized 1:1 to BES or SES. The primary endpoint was MACE (a composite of cardiac death, MI, or clinically-indicated TVR) at 9 months. Secondary endpoints include death, cardiac death, MI, ST (ARC defined), TLR and TVR. All patients are followed up to 5 years.
**Results:** 1707 patients were allocated to BES (857) and SES (850) patients. At 4 years, there was a clinical follow-up rate of over 96%, at which time the risk of MACE was lower in patients treated with BES than in those treated with SES (18.7% vs. 22.6%: p = 0.050). The RR of definite ST was 0.62 (p=0.09), which was largely attributed to a lower risk of very late definite ST between years 1 and 4 in the BES compared to the SES group (RR 0.20, p=0.004) demonstrating 80% relative risk reduction. An analysis of the correlation between MACE and definite stent thrombosis events showed that the benefit in favor of BES in terms of MACE was largely driven by a lower risk of MACE associated with definite VLST beyond the first year of follow-up.The 5-year analysis of LEADERS trial is ongoing.
**Conclusions:** Biodegradable polymer BES are non-inferior to durable polymer SES, and by reducing the risk of cardiac events associated with VLST, might improve long-term clinical outcomes. LEADERS final 5-year follow-up results will be reported for the 1st time during this presentation.

ORALS

## TCT-45

### Long Term Safety and Effectiveness of XIENCE V® Everolimus Eluting Coronary Stent System in Real-World Population: Three-Year Clinical Outcomes from the XIENCE V® USA Study

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**Background:** XIENCE V USA is a prospective, multicenter, single-arm, FDA required condition of approval study designed to examine the performance of XIENCE V® Everolimus Eluting Coronary Stent System (XIENCE V, Abbott Vascular, Santa Clara, CA) in a real-world all-comer population. The safety and effectiveness of XIENCE V in real world have been demonstrated previously with low rates of target lesion revascularization (TLR), cardiac death, MI and stent thrombosis (ST) at both 1 and 2 years. Whether these results of the XIENCE V are sustained at 3 years has not been reported, particularly regarding the very late ST.
**Methods:** A total of 5020 patients (1871 [37%] standard risk, and 3149 [63%] extended risk) were included in the long term follow-up cohort of the study. All clinical endpoint events were adjudicated independently by the Clinical Events Committee.
**Results:** Clinical Outcomes through 3 years in the overall population as well as the key subgroups for the extended risk population were shown in the table below. About 93% of patients remained in the study at 3 years. The overall very late ST between 1 and 3 years was 0.23% with 53.1% patients remained on dual antiplatelet therapy (DAPT) at 3 years.
**Conclusions:** Low event rates were sustained through 3 years for the overall population, with higher rates observed in certain high risk subgroups than the standard risk population as expected. Despite that half of the patients were off DAPT at 3 years, the very late ST between 1 and 3 years remained low as 0.23%. These results demonstrate continued safety and effectiveness of the XIENCE V in a highly complex, real-world patient population through 3 years.

**XIENCE V USA Clinical Outcomes Through Three Years**

| | Overall (N=5020) | Standard Risk (N=1871) | Extended Risk (N=3149) | AMI (N=667) | Renal Insufficiency (N=555) | Diabetic (N=1772) | Multivessel Stenting (N=655) | Bifurcation (N=509) | ISR (N=388) | Long Lesion (> 28 mm) (N=384) | CTO (N=129) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Cumulative ST (def/prob) | 1.16% (52) | 0.41% (7) | 1.62% (45) | 1.57% (9) | 2.58% (12) | 1.55% (24) | 1.86% (11) | 2.25% (10) | 3.13% (11) | 2.41% (8) | 0.92% (1) |
| Cardiac Death and ARC MI | 11.5% (547) | 7.4% (131) | 14.0% (416) | 15.8% (97) | 23.3% (123) | 15.2% (254) | 14.6% (91) | 11.6% (55) | 14.6% (54) | 15.5% (55) | 11.0% (13) |
| Cardiac Death and WHO MI | 6.6% (311) | 3.6% (64) | 8.4% (247) | 9.7% (59) | 14.9% (79) | 8.9% (148) | 7.9% (49) | 7.2% (34) | 7.3% (27) | 9.3% (33) | 5.9% (7) |
| TLF (ARC) | 15.5% (735) | 9.8% (175) | 18.9% (560) | 18.1% (111) | 26.1% (138) | 20.2% (337) | 20.8% (130) | 16.3% (77) | 27.8% (103) | 18.9% (67) | 19.5% (23) |
| TLF (WHO) | 13.1% (621) | 8.1% (144) | 16.1% (477) | 15.4% (94) | 21.2% (112) | 17.4% (290) | 16.9% (105) | 13.8% (65) | 25.9% (96) | 16.1% (57) | 16.9% (20) |
| TLR | 9.0% (426) | 5.8% (104) | 10.9% (322) | 9.5% (58) | 11.0% (58) | 11.7% (196) | 12.8% (80) | 9.3% (44) | 22.9% (85) | 10.1% (36) | 14.4% (17) |

Data are % (N).
ARC MI definition: elevation of troponin or CKMB > 3 URL for periprocedual PCI, > 5 URL for periprocedual CABG, and > 1 URL for spontaneous MI.
WHO MI definition: QMI per ECG or elevation of CK ≥ 2 URL with elevated CKMB in the absence of new pathological Q waves.
TLF = target lesion failure, a composite of cardiac death, MI attributed to target vessel, and TLR; ST = stent thrombosis; MI = myocardial infarction; ARC = Academic Research Consortium; WHO = world health organization; TLR = target lesion revascularization; AMI = acute myocardial infarction; ISR= in-stent restenosis; CTO = chronic total occlusion

## TCT-46

### Comparison of Polymer-Free BioFreedom™ Stents with Durable Polymer Taxus Liberté™ Stents: 3-Year Results from the BioFreedom First-In-Man Trial.

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**Background:** Drug-eluting stents reduce the rate of TLR compared with bare metal stents. However, there is still concern of an increased incidence of VLST potentially related to the durable polymer. The BioFreedom™ stent (BFD) releases Biolimus A9™, without the use of a polymer or binder. This trial aims to demonstrate the safety and effectiveness of the BioFreedom biolimus-eluting stent as compared to the Taxus Liberté™ pactilaxel-eluting stent (PES).
**Methods:** The BioFreedom FIM trial is a prospective, multi-center, randomized, single-blind study. 182 patients were enrolled and randomized to BFD Standard Dose (SD, 15.6 μg/mm), or BFD Low Dose (LD, 7.8 μg/mm), or Taxus Liberté™ DES at 4 sites in Germany. The first 75 patients received angio and IVUS FU at 4 months (1st cohort), the remaining patients received angio and IVUS FU at 12 months (2nd cohort). The primary endpoint was in-stent Late Loss (LL) at 12 months. The secondary endpoints are IVUS neointimal volume at 4 months; MACE (death, MI, emergent Bypass or clinically-driven TLR) and ST rates (ARC defined) at 30 days, 4 and 12 months, 2, 3, 4 and 5 years.
**Results:** The in-stent LL was non inferior in BFD SD vs.Taxus (Pnon-inferiority = 0.001) and trended towards superiority with medians of 0.17mm [0.09, 0.39] vs. 0.35mm [0.22, 0.57] for BFD SD compared to Taxus (Psup=0.11) at 12 months. At 2 years, the clinical FU for all patients was 99%. The BFD SD showed numerically lower rates of MACE (BD SD 6.8% vs. PES 10.0%) and TLR (BFD SD 3.4% vs. PES 6.7%). No stent thrombosis was seen in any groups up to 2 year. The 3-year clinical evaluation is ongoing.
**Conclusions:** This First-In-Man study has proven non-inferiority (with trend towards superiority) of the BioFreedom (polymer free stent versus TAXUS Liberté in the primary endpoint of in-stent LL. The safety and efficacy characteristics were comparable up to 2 years follow up with numerically lower MACE and TLR for BioFreedom. The BioFreedom FIM 3-year follow-up results will be reported for the 1st time during this presentation.